

90-DAY RESPONSE (this is a re-submission)

DCI Number: GDCI-128997-1598

Data Call-In Information

Company Name	ROTAM LIMITED
Company Address	7217 LANCASTER PIKE, SUITE A P.O. Box 640 HOCKESSIN, DE 19707
DCI Type	Generic
Issued Date	09/14/2017
90-Day Response Deadline	12/23/2017
CRM Information	Kettl, Brian
Chemical Name	Tebuconazole
Chemical Number	128997

90-Day Response Information

Resubmission	Yes
Tracking Number	CDX_DCI_2017_001671

DCI Level Documents

File Name	File Type	MIRID	CBI	Submitted Date
Agent Letter.pdf	Submission Cover Letter	N/A	N	12/22/2017

EPA Product Registration Number(s)

81598-2	I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."
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Guideline Requirement Number(s)

Guideline Requirement Number - 835.1110

Study Title	Activated sludge sorption isotherm
Protocol	N
Target Submission Date	09/14/2018
Use Pattern	A; BB; C; Q; X
Test Substance	TGA1
Time Frame	12 month(s)
Footnote(s)	15. This study is required only in support of antimicrobial uses. 34. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0003 .
Registrant Response	Offer to Cost Share

Uploaded Documents

File Name	File Type	MIRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N/A	Y	12/22/2017
Cover letter.pdf	General Correspondences	N/A	N	12/22/2017

Guideline Requirement Number - 835.3110

Study Title	Ready biodegradability
Protocol	N
Target Submission Date	09/14/2018
Use Pattern	A; BB; C; Q; X

Test Substance	TGAi			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 33. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0017 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 835.3220				
Study Title	Porous pot test			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAi			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 32. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0024 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 835.3240				
Study Title	Simulation Test-Aerobic Sewage Treatment-Activated Sludge			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAi			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 31. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0034 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017

Guideline Requirement Number - 835.3280				
Study Title	Simulation Tests to Assess the Biodegradability of Chemicals			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAi			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 30. EPA has a published final guideline for this study: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0152-0036 . The biodegradation study required is based on results of an Activated Sludge Respiration Inhibition test.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 850.2100				
Study Title	Avian acute oral toxicity test			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAi			
Time Frame	12 month(s)			
Footnote(s)	14. This study is required only in support of conventional uses. 23. Only passerine species toxicity data are required.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 850.3020				
Study Title	Honey bee acute contact toxicity			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAi			
Time Frame	12 month(s)			
Footnote(s)	8. Tier 1 study. USEPA. 2012a. "Honey Bee Acute Contact Toxicity" Ecological Effects Test Guidelines OCSPP 850.3020. EPA 712-C-019 14. This study is required only in support of conventional uses. 21. See also OECD 214: OECD.1998b. OECD Guidelines for the Testing of Chemicals. Test Number 214, Acute Contact Toxicity Test. http://www.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test_9789264070189-en			

Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 850.3030				
Study Title	Honey bee toxicity of residues on foliage			
Protocol	Y			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	<p>2. USEPA. 2012b. "Honey Bee Toxicity of Residues on Foliage." Ecological Effects Test Guidelines OCSPP 850.3030. EPA 712-C-018.</p> <p>9. Tier 1 study. Guideline 850.3030 data are required when the product formulation contains one or more active ingredient(s) having an acute LD50 of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide.</p> <p>14. This study is required only in support of conventional uses.</p> <p>41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 850.3040				
Study Title	Field testing for pollinators			
Protocol	Y			
Target Submission Date	09/14/2019			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	24 month(s)			
Footnote(s)	<p>1. USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.</p> <p>3. Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.</p> <p>14. This study is required only in support of conventional uses.</p> <p>20. See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf</p> <p>41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date

Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	NA	Y	12/22/2017
Cover letter.pdf	General Correspondences	NA	N	12/22/2017
Guideline Requirement Number - 850.3300				
Study Title	Modified Activated Sludge, Respiration Inhibition Test			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGA1			
Time Frame	12 month(s)			
Footnote(s)	<p>15. This study is required only in support of antimicrobial uses.</p> <p>18. The results of the Activated Sludge, Respiration Inhibition Test (ASRI), GLN 850.3300, will determine which of the four biodegradation tests are required. If the ASRI test results in an EC50 of less than or equal to 20 mg/L, then either the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, GLN 835.3280, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, GLN 835.3240, or (iii) the Porous Pot Test, GLN 835.3220 is required. If the ASRI test results in an EC50 greater than 20 mg/L, then the registrant is required to conduct either the (i) Ready Biodegradability, GLN 835.3110, (ii) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (iii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iv) the Porous Pot Test. If the Ready Biodegradability Study is conducted and passes, then no further testing is required. If, however, the pesticide fails the Ready Biodegradability study, then the (i) Simulation tests to assess the biodegradability of chemicals discharged in wastewater, (ii) the Simulation Test-Aerobic Sewage Treatment: A. Activated Sludge Units, or (iii) the Porous Pot Test is required.</p> <p>24. OECD Test Guideline 209 can also be used as guidance for this study, available online at http://www.oecd-ilibrary.org/content/book/9789264070080-en</p> <p>29. EPA published draft guidance under guideline 850.6800 and has since published final guidance for this study under guideline 850.3300: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0021.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	NA	Y	12/22/2017
Cover letter.pdf	General Correspondences	NA	N	12/22/2017
Guideline Requirement Number - 850.4100				
Study Title	Seedling Emergence and Seedling Growth			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	<p>6. Tier 2 data on monocots are required.</p> <p>14. This study is required only in support of conventional uses.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	NA	Y	12/22/2017
Cover letter.pdf	General Correspondences	NA	N	12/22/2017
Guideline Requirement Number - 850.4150				

Study Title	Vegetative Vigor			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	7. Tier 2 data on dicots and monocots are required. 14. This study is required only in support of conventional uses.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 850.4500				
Study Title	Algal Toxicity			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAI, TEP			
Time Frame	12 month(s)			
Footnote(s)	16. This study is required in support of both antimicrobial and conventional uses. 25. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028 . 38. Algal toxicity data required on two species of non-vascular plants (freshwater and marine diatoms).			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 850.4550				
Study Title	Cyanobacteria (<i>Anabaena flos-aquae</i>) Toxicity			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAI, TEP			
Time Frame	12 month(s)			
Footnote(s)	16. This study is required in support of both antimicrobial and conventional uses. 25. In a Federal Register Notice dated June 27, 2012, EPA split the Public Draft OPPTS 850.5400 test guideline into two test guidelines: OCSPP 850.4500 and OCSPP 850.4550. See "Final Test Guidelines; OCSPP 850 Series; Notice of Availability" 77 FR 38282, June 27, 2012. https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0028 .			
Registrant Response	Offer to Cost Share			

Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 850.6100				
Study Title	Environmental Chemistry Methods and Associated Independent Laboratory Validation			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAi			
Time Frame	12 month(s)			
Footnote(s)	14. This study is required only in support of conventional uses. 35. ECWILV needed for soil and water.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 875.1200				
Study Title	Dermal exposure--Indoor			
Protocol	Y			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 19. The following data/scenarios are needed: pressure treatment, liquid pour, sapstain, brush/roller, and airless sprayer. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 875.1400				
Study Title	Inhalation exposure--indoor			
Protocol	Y			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			

Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 19. The following data/scenarios are needed: pressure treatment, liquid pour, sapstain, brush/roller, and airless sprayer. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 875.1700				
Study Title	Product Use Information			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 22. Product use data is needed to clarify uses (particularly the use of plastics in toys), application rates and wood retentions, and application equipment.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - 875.2100				
Study Title	Foliar dislodgeable residue dissipation			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	14. This study is required only in support of conventional uses. 28. Foliar dislodgeable and turf transferrable residue dissipation data are required for post-application worker or residential exposure.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017

Guideline Requirement Number - 875.2300				
Study Title	Indoor surface residue dissipation			
Protocol	Y			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	12 month(s)			
Footnote(s)	15. This study is required only in support of antimicrobial uses. 17. The wipe study is based on the need to assess dermal and incidental oral exposures to children (age 1-2) playing on pressure treated decks and play sets. 39. A waiver may be requested for all applications if a residue screening level default at 100% of the application rate does not trigger risk concerns. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1196				
Study Title	Whole Sediment: Chronic toxicity to saltwater invertebrates			
Protocol	Y			
Target Submission Date	09/14/2019			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAI			
Time Frame	24 month(s)			
Footnote(s)	16. This study is required in support of both antimicrobial and conventional uses. 37. Chronic sediment toxicity data required on one species of estuarine/marine amphipod. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1197				
Study Title	Whole Sediment: Chronic toxicity to freshwater invertebrates			
Protocol	Y			
Target Submission Date	09/14/2019			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAI			
Time Frame	24 month(s)			

Footnote(s)	16. This study is required in support of both antimicrobial and conventional uses. 36. Chronic sediment toxicity data required on two freshwater species (an amphipod and a midge) in support of conventional uses. Only the freshwater amphipod data are required in support of antimicrobial uses. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1311				
Study Title	Honey bee adult acute oral toxicity			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGA1			
Time Frame	12 month(s)			
Footnote(s)	10. Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en 14. This study is required only in support of conventional uses.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1312				
Study Title	Honey bee larvae acute oral toxicity			
Protocol	N			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGA1			
Time Frame	12 month(s)			
Footnote(s)	13. Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (<i>Apis mellifera</i>) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en 14. This study is required only in support of conventional uses.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1313				

Study Title	Honey bee adult chronic oral toxicity			
Protocol	Y			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAI			
Time Frame	12 month(s)			
Footnote(s)	11. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (<i>Apis mellifera</i> , <i>Bombus</i> spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: https://www.efsa.europa.eu/en/efsajournal/pub/3295 14. This study is required only in support of conventional uses. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1314				
Study Title	Honey bee larvae chronic oral toxicity			
Protocol	Y			
Target Submission Date	09/14/2018			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAI			
Time Frame	12 month(s)			
Footnote(s)	12. Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (<i>Apis mellifera</i>) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf 14. This study is required only in support of conventional uses. 41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1315				
Study Title	Semi-field testing for pollinators			
Protocol	Y			
Target Submission Date	09/14/2019			
Use Pattern	A; BB; C; Q; X			
Test Substance	TGAI, TEP			
Time Frame	24 month(s)			

Footnote(s)	<p>5. Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.</p> <p>14. This study is required only in support of conventional uses.</p> <p>26. Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (<i>Apis mellifera</i> L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007.</p> <p>http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en.</p> <p>27. For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. <i>Bul OEPP/EPPO Bulletin</i> 22: 613-616.</p> <p>41. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Guideline Requirement Number - SS-1316				
Study Title	Field trial of residues in pollen and nectar			
Protocol	Y			
Target Submission Date	09/14/2019			
Use Pattern	A; BB; C; Q; X			
Test Substance	TEP			
Time Frame	24 month(s)			
Footnote(s)	<p>4. Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.</p> <p>14. This study is required only in support of conventional uses.</p> <p>40. A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar. 1) Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under. 2) Consideration of the attractiveness of the selected crop to pollinators. 3) Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time. 4) Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators. 5) Consideration of the market proportion of the selected target crop(s).</p>			
Registrant Response	Offer to Cost Share			
Uploaded Documents				
File Name	File Type	MRID	CBI	Submitted Date
Attempt to Cost Share 8570-32.pdf	Form 8570-32 Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	N.A.	Y	12/22/2017
Cover letter.pdf	General Correspondences	N.A.	N	12/22/2017
Submitter Information				
Submitter	Anna Armstrong			
Submitted Date	12/22/2017			